

What is claimed is:

1. A system for placing a stent into the side branch of an arterial bifurcation, the system including:

5

an inflatable balloon located at a distal portion of a stent delivery system, the stent delivery system having an outer shaft with a longitudinal length, the outer shaft having a distal end that is fixedly attached to the proximal end of the balloon;

10

a pre-deployed side branch stent mounted coaxially onto the balloon for placement into the side branch of an arterial bifurcation, the stent having a proximal end and a distal end;

15

a guide wire; and

20

a main guide wire tube having a proximal end and a distal end and having an interior lumen that allows the stent delivery system to be moved slideably over the guide wire, the main guide wire tube being fixedly attached to the balloon at a location that is in close proximity to the proximal end of the stent.

25

2. The system of claim 1 where the guidewire tube extends in a generally longitudinal direction onto a proximal portion of the balloon.

3. The system of claim 1 where the guidewire tube extends in a proximal direction onto the outer shaft of the stent delivery system.
4. The system of claim 1 where at least part of the guide wire tube is  
5 fixedly attached to the outside of the balloon.
5. The system of claim 1 where at least part of the guidewire tube is located within the balloon.
6. The system of claim 1 where the guide wire tube is made from a  
10 flexible elastomer that is fixedly attached along its entire length to both the balloon and the outer shaft.
7. The system of claim 1 where the guide wire tube has a distal opening;  
15 at its distal end, the distal opening being situated within a distance of less than 1.0 mm from the proximal end of the stent.
8. The system of claim 1 where the guide wire tube is formed in two  
20 separate portions, a first portion being a proximal portion that is fixedly attached to the outer shaft of the stent delivery system and a second portion that is a distal portion that is fixedly attached to the balloon.
9. The system of claim 1 where the guide wire tube is formed with a  
25 longitudinal opening situated between a first portion of the tube that is a proximal portion that is fixedly attached to the outer shaft of the stent delivery system and a second portion of the tube that is a distal portion that is fixedly attached to the balloon.

10. The system of claim 1 where the stent has a multiplicity of circumferential sets of strut members, the normal to the plane of the most proximal circumferential set of strut members making an angle that is greater than 20 degrees relative to the longitudinal axis of the balloon.

5

11. The system of claim 1 where the stent is coated with at least one drug whose effect is to decrease restenosis at the site of the arterial bifurcation by elution of the at least one drug into the wall of the artery in the region where the stent is placed.

10

12. The system of claim 11 where the drug is selected from the group consisting of a cytostatic drug, a cytotoxic drug, sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), everolimus and other analogs of sirolimus or everolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl-rapamycin, 7-epi-thiomethyl-rapamycin, 7-demethoxy-rapamycin, 32-demethoxy, 2-desmethyl, proline and paclitaxel.

15

20

13. The system of claim 12 where there is an increased amount of the at least one drug on a proximal portion of the stent as compared to the amount of drug on a distal portion of the stent.

25

14. The system of claim 1 where the stent is coated with a drug for the purpose of decreasing subacute thrombosis.

15. The system of claim 14 where the drug is heparin.

5 16. The system of claim 1 where the balloon when inflated has a generally uniform diameter for most of its length and an outward flare to a larger diameter where the inflated balloon is situated under the proximal end of the stent.

10 17. The system of claim 1 where the balloon when inflated has a generally uniform diameter for most of its length and is a compliant balloon that readily expands to a greater diameter when not confined by the walls of the side branch artery.

15 18. The system of claim 1 where the length of the stent is shorter on the side where the deployed stent's proximal end is situated at the carina of the bifurcation and longer on the side of the deployed stent that reaches the obtuse point of the bifurcation, the difference in length being greater than 1.0 mm.

20 19. The system of claim 1 further including a main branch stent, the main branch stent having the area for each cell of the deployed stent that is less than  $4.0 \text{ mm}^2$  and each cell having a perimeter length that is greater than 10 mm.

25 20. The system of claim 1 where the stent delivery system also includes an inner shaft having a guide wire lumen where the distal end of the guide wire lumen is located at the distal end of the stent delivery system.

21. The system of claim 1 where the stent delivery system also includes an elongated distal tip placed distal to the balloon, the distal tip having a guide wire lumen, the distal end of the guide wire lumen being located at the distal end of the distal tip and the proximal end of the guide wire lumen being located between the distal end of the balloon and the distal end of the distal tip.

5

22. The system of claim 1 where the distal end of the stent delivery system includes a fixed guide wire attached to the distal portion of the stent delivery system, the fixed guide wire extending in a direction distal to the balloon.

10

23. A pre-deployed balloon mounted at a distal portion of a catheter shaft the pre-deployed balloon being folded with an even number of folds formed as pairs, each pair of folds being symmetrically located around the circumference of the balloon.

15

24. The balloon of claim 23 where there are exactly two folds.

25. The balloon of claim 23 where there are exactly four folds.

20

26. A means to prevent the rotation of a stent mounted on an inflatable balloon, the means including placing an elastomer tube around the balloon, the elastomer tube expanding elastically as the balloon is inflated.

25

27. The means of claim 26 where both the interior surface of the elastomer tube and the external surface of the balloon are each treated with a chemical to increase their lubricity.

5 28. A system for placing a stent into the side branch of an arterial bifurcation, the system including:

10 an inflatable balloon located at a distal portion of a stent delivery system, the stent delivery system having an outer shaft with a longitudinal length, the outer shaft having a distal end that is fixedly attached to the proximal end of the balloon;

15 a pre-deployed stent mounted coaxially onto the balloon for placement into the side branch of an arterial bifurcation, the stent having a proximal end and a distal end;

a guide wire; and

20 a main guidewire tube that allows the stent delivery system to be moved slideably over the guide wire, the main guide wire tube having a proximal portion having a distal end and the main guide wire tube also having a distal portion which is not directly connected to the stent delivery system, the distal portion extending continuously in a distal direction from the  
25 distal end of the proximal portion, the distal end of the proximal portion being fixedly attached to the balloon at a point that is in close proximity to the proximal end of the stent.

29. The system of claim 28 where at least part of the proximal portion of the guide wire tube is located within the balloon.

30. The system of claim 28 where the proximal portion of the guide wire tube is made from a flexible elastomer that is fixedly attached along its entire length to both the balloon and the outer shaft.

31. The system of claim 28 where the distal end of the proximal portion of the main guide wire tube is attached to the balloon within a distance of less than 3.0 mm from the proximal end of the stent.

32. The system of claim 28 where the stent is coated with at least one drug whose effect is to decrease restenosis at the site of the arterial bifurcation by elution of the at least one drug into the wall of the artery in the region where the stent is placed.

33. The system of claim 32 where there is an increased amount of the at least one drug on a proximal portion of the stent as compared to the amount of drug on a distal portion of the stent.

34. The system of claim 28 where the stent is coated with an anti-thrombogenic drug for the purpose of decreasing subacute thrombosis.

35. A method for stenting an arterial bifurcation, in a human subject, the method including the following steps:

- a. placing a main guide wire into and through a proximal artery and a main branch of that artery;
- b. advancing a stent delivery system that includes a main branch stent over the guide wire and deploying the main stent with its longitudinal center located approximately over the ostium of a side branch artery of the proximal artery and removing the stent delivery system from the subject;
- c. inserting a side branch guide wire through the side of the deployed main stent;
- d. advancing a balloon angioplasty catheter over the side branch guide wire until a balloon located at a distal portion of the balloon angioplasty catheter is approximately centered within the ostium of the side branch artery and inflating the balloon to open the struts of the main stent to form an opening at the ostium of the side branch artery that is approximately the same area as the ostium of the side branch artery;
- e. deflating the balloon from step d) above and removing the balloon angioplasty catheter from the human subject;
- f. advancing a stent delivery system having two guide wire lumens over both the side branch guide wire and the main guide wire, the stent delivery system having an inflatable balloon and a side branch stent both located at a distal portion of the stent delivery system, the stent delivery system also having a main guide wire tube whose lumen is one of the two guide wire lumens of the stent delivery system, at least part of the main guide wire tube being fixedly attached to the balloon at a location that is in close proximity to the proximal end of the side branch stent, the side branch guide wire passing through



the inner shaft of the stent delivery system and the main guide wire passing through the main guide wire tube that is fixedly attached to the balloon;

- g. advancing the stent delivery system for the side branch stent until the stent's proximal end is placed in close proximity to the carina of the bifurcation;
- h. inflating the balloon so as to deploy the side branch stent against the walls of the side branch artery of the bifurcation;
- i. deflating the balloon and removing the side branch stent delivery system from the human subject; and
- j. removing the side branch guide wire and the main guide wire from the human subject.

36. The method of claim 35 where the side branch stent is an angulated side branch stent.

37. A method for stenting an arterial bifurcation of a human subject, the method including the following steps:

- a. inserting a side branch guide wire into and through the ostium of a side branch of a bifurcated artery;
- b. placing a main guide wire into and through a proximal artery and main branch artery of the bifurcation;
- c. advancing a side branch stent delivery system that includes a side branch stent having an attached main guide wire tube over the side branch guide wire with the main guide wire passing through the main guide wire tube, the side branch stent being advanced until its proximal end is in close proximity to the carina of the side branch;

d. deploying the side branch stent into the side branch artery and removing the side branch stent delivery system and the side branch guide wire from the human subject;

e. advancing a main stent delivery system that includes a main stent over the main guide wire and deploying the main stent with its longitudinal center located approximately over the ostium of the side branch artery and removing the main stent delivery system from the human subject;

f. advancing a side branch guide wire through the side of the deployed main stent at the site of the ostium of the side branch artery;

g. advancing a balloon angioplasty catheter over the side branch guide wire until a balloon located at a distal portion of the balloon angioplasty catheter is approximately centered within the ostium of the side branch artery and inflating the balloon to open the struts of the main stent to form an opening at the ostium of the side branch artery that is approximately the same area as the ostium of the side branch artery; and

h. deflating the balloon from step g) and removing both the balloon angioplasty catheter and the side branch guide wire from the human subject.

38. The method of claim 37 where the side branch stent is an angulated side branch stent.

39. The method of claim 37 where the main guide wire tube has a proximal portion that is attached to the balloon of the side branch stent delivery system and main guide wire tube has a distal portion that

extends freely from the distal end of the proximal portion of the main guide wire tube and is not directly attached to any part of the side branch stent delivery system.